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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/771,861 | 02/03/2004 | Kazuo Ando | PC9960D | 3504 |
| 28523 | 7590 | 09/02/2004 | EXAMINER | |
| | | | PATEL, SUDHAKER B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |

DATE MAILED: 09/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/771,861 | ANDO ET AL. | |
| | Examiner | Art Unit | |
| | Sudhaker B. Patel, D.Sc.Tech. | 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 February 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/3/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' communication paper dated 2/3/04 is acknowledged. The claims in this application are the claims 1-15.

After further review and consideration, this application is found not ready for allowance in, as is state for the reasons stated bellow.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 2/3/04 is being considered by the examiner. Signed copy of Form PTO 1449 is enclosed with this communication for applicants' record.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 12, 13, are rejected under the judicially created doctrine of double patenting over claims 1, 28, 29 of U. S. Patent No. 6294558 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The instant invention differs from the ref.'558 by reciting broader scope for invention of the compounds and their composition, and method of use as claimed herein. See claim 1 in column 167 line 19-67, composition Claim 28 in column 172, lines 58-61, and method of use for the composition claim 29 in column 172, lines 62-67 respectively. Therefore, if instant invention is granted a patent, the same will extend the monopoly of the ref.'558.

Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,9,10,11 of U.S. Patent No. 6727238. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention differs from the ref.'238 by reciting broader scope for invention of the compounds and their composition, and their use as claimed by the ref.'238. See composition claim 10 in column 170 lines 1-4, and method of use claim 11 in column 170 in line 5—10 respectively. Therefore, if instant invention is granted a patent, the same will extend the monopoly of the ref.'238.

Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,9,10 of U.S. Patent No. 660895. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention differs from the ref.'895 by reciting broader scope for invention of the compounds and their composition, and their use as claimed by the ref.'895. See claim 1 in columns 155-157, composition claim 9 in column 158, lines 50-61, and method of use claim 10 in column 158, lines 62-65 respectively. Therefore, if instant invention is granted a patent, the same will extend the monopoly of the ref.'895.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Tschesche et al (Tetrahedron, 19,621-34(1963, also cited as Chemical Abstract DN 59:35876). Tschesche teaches making of a compound with CRN # 27918-19-0(= Benzenesulfonamide, 4-hydrazino-, hydrochloride) as claimed herein.

6. Claims 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Klockow et al (EP 743304 dated 11/1996, also cited as Chemical Abstract DN 126:59948). Klockow teaches making of compounds with CRN # 4392-54-5(= Benzenesulfonamide, 4-hydrazino-); CRN # 90154-08-8(= Benzenesulfonamide-, N-ethyl-4-hydrazino-); CRN # 184708-11-0(+ Benzenesulfonamide, N-(1,1-bimethylethyl)-4-hydrazino-) as claimed herein.

7. Claims 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Crippa et al (Gazzetta Chimica Italia, 72,97-9(1942), also cited as Chemical Abstract DN 37:3564). Crippa teaches making of a compound with CRN # 4392-54-5(= Benzenesulfonamide, 4-hydrazino-) as claimed herein.

8. Claims 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lombardino et al (J. Medicinal Chemistry, 24/7,830-4(1981), also cited as Chemical Abstract DN 95:17984). Lombardino teaches making of a compound with CRN # 877-66-7(=Hydrazine, [4-(methylsulfonyl)phenyl]-) as claimed herein.

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9. Claims 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Flores et al (J. of Pharmacology and Experimental Therapeutics, 174/3, 463-72(1970), also cited as Chemical Abstract DN 73:106778). Flores teaches making of a compound with CRN # 4837-28-9(= Hydrazine, [4-difluoromethyl]sulfonyl]phenyl-) as claimed herein.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claim 12,13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a step or process asserted utility or a well established utility.

The claim is reciting a method of use and the pharmaceutical composition for a medical condition in which prostaglandins are implicated as pathogens.

Claim 12, 13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a step or process of making and a step or process of administration asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 1 is also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1). Claim 1 recites variables A, R1 as (where applicable) partially saturated or unsaturated heterocycle or partially saturated or unsaturated carbocycle, aryl, and heteroaryl. It is not very clear as to what is exactly and definitely being recited. Recitation of heterocycle ring(s) from the working example(s) is required.

(2). Claim 1 recites variable R1 as: "optionally substituted". The claim remains silent about the exact position of the substituent. Also, the proviso as recited remains silent about the exact meaning of heteroaryl for R1 component. Correction is required.

Claim Objections

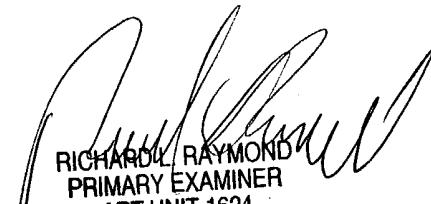
14. Claims 10,11 are objected to because of the following informalities: The claims recite more than 150 (see pages 215-226) compounds consisting of more than one core. E.g. pyrazole, furanone, pyrrole, imidazole, thiophene, thiazole, oxazole, and others. Rule 141(a) provided that ultimate species may only be listed, up to a reasonable number, in a situation where one has an allowable generic claim. A total of more than 150 recited in pages 215-226 are not a reasonable number. Appropriate correction is required.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is (571) 272-0671. The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on (571) 272 0674 or Sr. Examiner Mr. Richard Raymond at (571) 272 0673 or Mr. James Wilson at (571) 272-0661. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sudhaker B. Patel, D.Sc. Tech.
August 27, 2004.



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